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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,631	03/01/2002	Stephan Jaeger	1803-335-999	3750

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	14

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,631	JAEGER, STEPHAN	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-14* is/are pending in the application.

4a) Of the above claim(s) *1-5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 6-14 in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant application. ***Information Disclosure Statement***

3. The information disclosure statement filed 10/7/2002 is acknowledged. However, four of the references (0 680 969, 0 324 474, 0 624 161 and 0 286 028) have not been considered because Applicant failed to provide a translation of the claimed references and thus no meaningful interpretation of the information referred to therein could be ascertained. It is suggested submitting a translation of those references for consideration of the information referred to therein.

Specification

4. The disclosure is objected to because of the following:

(a) The priority information is not recited in the first sentence on the first page of the specification (see 37 CFR 1.78(a) and MPEP 201.11). It is suggested amending the disclosure by reciting the priority information in the first sentence on the first page of the specification.

(b) The use of the trademark "Wisconsin Package" at page 8 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory matter. Claim 1 is drawn to a polynucleotide, which reads on a product of nature such as e.g., a mRNA. The claim should be amended to indicate the hand of the inventor, for example, the insertion of "isolated" in connection with control nucleic acid to identify a product not found in nature (see MPEP 2105).

Claim Rejections - 35 USC § 112 first paragraph: Lack of adequate Written Description

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a control nucleic acid, composition and kit for amplification of a target nucleic acid region, wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to said target nucleic acid region or to the complementary strand of said target nucleic acid region. The claims further encompass wherein said target nucleic acid region comprises a probe binding site and/or a primer binding site and said control nucleic acid comprises a sequence that is parallel complementary to the probe binding site or the primer binding site of said target nucleic acid or the complementary strand of the probe binding site or primer binding site of said target nucleic acid region. At page 7 of the specification, Applicant discloses that a preferred control nucleic acid according to the present invention covers essentially the region of the target nucleic acid to be determined characterized in that the region of said control nucleic acid covering essentially the region of said target nucleic acid to be determined or the complement of said target nucleic acid contains at least one contiguous sequence of at least 8 nucleotides being essentially parallel-complementary to said target nucleic acid or to the complementary strand of said target nucleic acid. Applicant further discloses that covering essentially the region of the target nucleic acid to be determined in the context means, that this region of the control nucleic acid consists of one or more parts, whereby the sequence of each part is essentially identical or essentially parallel-complementary to the according part of the target nucleic acid region to be determined or to the complementary strand. Applicant discloses that therefore, this region of the control nucleic acid is either essentially identical, essentially parallel-complementary or in part essentially parallel-

complementary, whereas the other part is essentially identical to the relevant region of the target nucleic acid region to be determined or to the complementary strand of the target nucleic acid. At page 11, Applicant discloses that a control nucleic acid according to the present invention can be constructed on the basis of the sequence of the coding strand of RNA or DNA or the strand complementary thereto. Beginning at page 21, Applicant discloses in the specification 6 examples which identifies about 8 nucleic acid sequences (probe and primers) having at least one contiguous sequence of at least 8 nucleotide in length essentially parallel complementary to an HCV (hepatitis C virus) target nucleic acid region or the complementary strand of the HCV target nucleic acid region.

The claims as written encompass a large genus of nucleic acid sequences not adequately described or disclosed. More specifically, the specification does not provide sufficient written description to support the large genus encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "Applicant must convey with reasonable clarity to those in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, "*whatever is now claimed*". (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invent what is claimed" (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acid sequences, regardless of the complexity or simplicity of the method of isolation. See *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd,* 18 USPQ2d 1016. In *Fiddes v. Baird,* 30 USPQ2d 1481, 1483, claims

directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co.,43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention. "*Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012,10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an Applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention. "*Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966".
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, the nucleic acid sequences encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species disclosed herein is not a

representative of the genus because the genus is highly variable. Accordingly, the specification fails to show that Applicant was, in fact "in possession of the claimed invention" at the time the application for patent was filed. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is separable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullis (US 4,683,202, July 28, 1987). Regarding claims 6-14, Mullis et al. teach a control nucleic acid sequence and composition comprising a target nucleic acid and a control nucleic acid sequence for use in an amplification reaction wherein said control nucleic acid sequence comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to said target nucleic acid region (see example 1, col. 15, lines 45-56) and wherein said target nucleic acid region comprises a primer binding site and the control nucleic acid sequence comprises a sequence that is parallel complementary to the primer binding site of the target nucleic acid (see example, col. 15, lines 45-56). The reference further teaches wherein the target region comprises a probe binding site and the control nucleic acid sequence comprises a sequence that is parallel complementary to the probe binding site of the target nucleic acid, (see example 5, lines 16-23) and wherein the composition further comprises primers for amplification

(example 5, col. 21, lines 30-38). Therefore, Mullis meets all of the claimed limitations of claims 6-12 of the instant invention.

10. Claims 6, 8, 9, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nadeau et al. (5,840,487, November 24, 1998). Regarding claims 6, 8, 9, 11, Nadeau et al teach a control nucleic acid and composition comprising a target nucleic acid and control nucleic acid for use in an amplification reaction wherein the control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to the target nucleic region and wherein said target nucleic acid region further comprises a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the probe binding site of the target nucleic acid (see column 8, lines 1-41). Therefore, Nadeau et al meets all of the claimed limitations of claims 6, 8, 9, 11 of the instant invention.

11. Claims 6, 7, 9, 10, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsang (5,837,442, November 17, 1998). Regarding claims 6, 7, 9, 10, 12-14, Tsang teaches a control nucleic acid sequence, composition and kit, wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotide in length essentially parallel complementary to a target nucleic region. The reference further teaches wherein said target nucleic acid region comprises a primer binding site and said control nucleic acid sequence comprises a sequence that is parallel complementary to the primer binding site of said target nucleic acid or to the complementary strand of said target nucleic acid (Col. 5, lines 24-45). The reference further teaches wherein the nucleic acid sequences are in the form of a kit (col. 8, lines 17-27). Therefore, Tsang et al. teach the limitations of the claimed invention of the claims recited above.

Conclusion

12. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

Cynthia Wilder

Cynthia B. Wilder, Ph.D.
Examiner
Art Unit 1637

cbw
August 4, 2003